

REMARKS

The rejection of claims 19 to 24 as being anticipated by Kitaevich et al (US Patent 6,471,872) is traversed. To further distinguish Kitaevich et al, independent claim 19 has been amended to require that the signal threshold be “automatically determined by the controller”.

Kitaevich et al do not disclose a controller:

“storing a **baseline feedback signal generated by the biosensor** during an initial phase of blood filtration treatment, said controller reducing the controlled filtration if the feedback signal exceeds the feedback signal threshold, wherein the **signal threshold is automatically determined by the controller and is a function of the baseline feedback signal.**” [Independent claim 19 (emphasis supplied)]

The claimed invention includes a biosensor that generates a “baseline feedback signal” that is stored by the controller and later used to automatically determine a signal threshold.

Kitaevich et al, col. 3, lns. 63-67, discloses a hemofiltration controller that has threshold levels selected by a human operator. As pointed out in the Action, Kitaevich et al, col. 9, lns. 16-35, disclose a controller that monitors certain conditions of the patient. Kitaevich et al do not disclose generating a baseline signal using a sensor or applying the baseline signal to automatically determine a signal threshold. The sections of Kitaevich cited the Action do not address a baseline feedback signal:

(i) at col. 8 line 60 to col. 9 line 6 Kitaevich teaches a manual mode of pumping rates in which the controller applies “fixed voltages” to the pumps and an automatic mode wherein a “desired hemofiltration amount or rate [is] programmed into the

controller.” There is no suggestion of a baseline being used to set the manual mode or automatic mode.

(ii) at col. 8 lines 35 to 45 Kitaevich et al teach that alarms are generated when limits are exceeded (see col. 8, ln. 43-46) but do not suggest that limits be determined based on a baseline measurement.

(iii) at col. 9, lns. 36 to 45 Kitaevich et al provide a general statement that parameter data is evaluated by the controller which modifies rates of infusate, filtration and blood pumping. There is no Kitaevich teaching that parameter data is compared to a threshold set using a baseline measurement.

Kitaevich et al would not have rendered the claimed invention to have been obvious, because Kitaevich et al do not disclose or suggest obtaining a baseline feedback signal or setting a threshold level automatically as a function of the base line signal.

The grounds for patentability of the dependent claims further include:

(i) Kitaevich et al do not disclose a threshold signal that is automatically determined based on a sum of a feedback signal obtained during an initial phase of a treatment of the patient and a predetermined current feedback signal change. *See* claim 21

(ii) Kitaevich et al do not disclose a control step of automatically **increasing** the reduced filtrate flow, if the feedback signal exceeds the threshold. *See* claim 25.

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All claims are in good condition for allowance. If any matter remains outstanding, the Examiner is requested to telephone the undersigned attorney. Prompt reconsideration and allowance of this application are requested.

Respectfully submitted,

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